

## REMARKS

Claims 35-38, 42-47, and 50-55 are pending in the application. Claims 39-41, 48, and 49 have been cancelled without prejudice. Claims 35, 45, and 46 have been amended. No new matter is added by these amendments. Support for the amendments is found at least in claims 3, 4, 7, and 13 as originally filed, and in the specification at page 6, line 4.

New claims 52-55 have been added. These new claims do not incorporate any new matter. Support for the subject matter of each of the new claims is found at least in the specification at page 6, lines 6-11 and 2-3.

### **I. Rejection under 35 U.S.C. § 112 – second paragraph.**

The Examiner has rejected claims 35-51 under 35 U.S.C. § 112, second paragraph, asserting that these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. As the rejections are premised on various grounds, each will be addressed in turn.

The Examiner rejects claim 35 “part a,” asserting the phrase “for monomers containing at least one structural element (A) derived from a carboxylic acid” renders the claim indefinite. Claim 35 recites an interactive system that includes one surface of a plastic material from monomers containing at least one structural element (A) that is derived from a carboxylic acid. The claims further recites that the plastics material is a polymethacrylate polymer, a polyvinyl ester polymer, or copolymers thereof. Accordingly, the applicants submit that claim 35 definitely recites the specific structures of the monomers that contain at least one structural element (A) that is derived from a carboxylic acid, when read in light of the description in the specification at, *e.g.*, pages 3-5, as is proper.

The Examiner also rejects claim 35 “part (a)” and “part (b)” for use of the parenthetical symbols “(A)” and “(B)”. The Examiner states that use of the parenthetical renders the claim unclear. The applicants disagree with the Examiner’s analysis, and traverse the rejection.

The use of the parenthetical symbols does not make the claims unclear. It is apparent precisely what the plastic material that contains monomers having the structural element (A) is, as these materials are recited within the claim. It is clear precisely what the linker that contains the structural element (B) is. The specification provides an unambiguous definition of structural element (A), spec. at 3. A person of skill could have easily ascertained the portion of the

specified linker that is capable of forming a hydrogen bond, for such analysis requires only a basic knowledge of chemistry.

The use of the parenthetical symbols is merely a device that allows the applicants to better specify the specific portion of the monomer and the specific portion of the linker between which the recited “stable interaction . . . which cannot be reversed by pH values in the range of from 2 to 13 or temperatures up to 60°C” exists. Thus, rather than render the claim indefinite, the parenthetical symbols serve to more precisely and accurately describe the invention.

The Examiner states that claim 35, part (b) is vague and indefinite for the recitation of “at least one structural element (B) capable of establishing a hydrogen bond.” The applicants traverse the rejection. Claim 35, part (b) recites that the linker is polyalkylene glycol, polyalkylene imine, polyalkylene amine, polyoxazilin, or polyalkylene sulfide. Determination of the portion(s) of these compounds that is capable of forming a hydrogen bond would have been easily and routinely carried out by a person of skill. Use of the phrase does not render the claim indefinite.

The Examiner has rejected claims 36 and 37, asserting that these claims recite overlapping, and, therefore, improper Markush groups. The applicants respectfully traverse the rejection. Classes of elements recited in the Markush group may be overlapping without making the claim indefinite, as long as each of the classes recited is an art-known and understood classification. See, M.P.E.P. 2173.05(h) (“The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claims unclear. For example, the Markush group, ‘selected from the group consisting of amino, halogen, nitro, chloro, and alkyl’ should be acceptable even though ‘halogen’ is generic to chloro.”) In the present case, each of the classes of elements recited in the Markush groups has a definite meaning, well known to a person of skill in the art. No confusion or lack of clarity results from the use of classes that may be overlapping.

The Examiner has rejected claim 45 for an “improper antecedent basis problem.” The applicants have amended claim 45 to recite “The interactive system . . . .” Accordingly, the Examiner’s rejection is no longer applicable.

The Examiner has rejected claim 47 for indefiniteness on the basis that it is a “omnibus-type claim” and therefore fails to point out what is included or excluded by the claim language. The applicants traverse this rejection. Claim 47 is a dependent claim from claim 35. Thus, one

can discern the metes and bounds of the claims by reading claim 47 and claim 35 in accordance with standard practice. In contrast, an omnibus claim is, as follows: “a device substantially as shown and described [in the specification].” M.P.E.P. 2173.05(r). Such claims are clearly indefinite as they fail to point out what specific elements in the specification are claimed. This is different from the present case as claim 47 recites those elements that are intended to be encompassed in the claim; accordingly, claim 47 is not indefinite.

The Examiner objects to claims 48 and 49. Claims 48 and 49 have been cancelled without prejudice.

The Examiner has rejected claim 51 as vague and indefinite in reciting “adapted for treatment.” The applicants traverse this rejection. As would have been known to a person of skill in the art at the time the application was filed, adapted for treatment of the various recited disorders encompasses modifications of the type of surface plastic material, linker, substance, and/or delivery vehicle, suitable for therapeutic or diagnostic effects in the varying recited diseases or disorders.

The Examiner has also rejected claim 51, stating that claim 51 “is indefinite in reciting improper Markush groups.” However, the Examiner does point out exactly what she considers to be improper about the Markush groups, and it is not readily apparent to the applicants. If the Examiner is rejecting claim 51 on the basis of overlapping classifications, the applicants reiterate by reference the argument made previously with respect to claims 36 and 37. If this is not the basis of the impropriety which the Examiner perceives, it is respectfully requested that she make clear the basis of the rejection, if it is maintained.

## **II. Rejections Under 35 U.S.C. § 102(b) and/or (e).**

The Examiner has made three rejections under 35 U.S.C. § 102(b) and/or (e) of varying subsets of the pending claims based upon three prior art patents: (i) U.S. Patent No. 4,086,199; (ii) U.S. Patent No. 4,575,539; and (iii) U.S. Patent No. 5,410,016.

Specifically, the Examiner has rejected claims 35-36, 39-43, and 47 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,086,199 of Daniel (“Daniel”). As basis for the rejection, the Examiner asserts that Daniel discloses an interactive system including “latex [sic] polymer particles” having a plastic material (core) that comprises alkylacrylates and methacrylates and a cross-linker comprising polyethylene glycol dimethacrylate which gives the

polymer particles greater resistance to solvents. According to the Examiner, Daniel teaches that biologically active substances such as proteins are coupled or absorbed into the carrier particle.

The Examiner has rejected claims 35, 36, 39-42, 44, and 47-51 under 35 U.S.C. § 102(b) asserting that they are “inherently anticipated” by U.S. Patent No. 4,575,539 of DeCrosta, *et al.* (“DeCrosta”). The Examiner states that DeCrosta discloses an acrylic swelling agent, methyl methacrylate or acrylic acid, and a cross-linking agent that is ethylene glycol or dimethacrylate. The Examiner explains that the hydrogel beads of DeCrosta are loaded with pharmaceutically active compositions by coupling the compositions with the linker by swelling the hydrogel. Finally, the Examiner states:

Since all the elements recited in the claimed invention appear to be disclosed by DeCrosta, it is maintained that the features recited in the claimed invention, *i.e.*, a stable interaction exists between the surface and the linker which comprises hydrogen bonds and which cannot be reversed by pH in the range of from 2-13 or temperatures up to 60C, are inherently taught by DeCrosta.

OA at page 6.

The Examiner has The Examiner has rejected claims 35-51 under 35 U.S.C. § 102(e) as being “inherently anticipated” by U.S. Patent No. 5,410,016 of Hubbell, *et al.* (“Hubbell”). The Examiner asserts that Hubbell discloses an interactive system comprising photopolymerizable biodegradable hydrogels used as tissue contact materials or controlled release carriers. Specifically, the system has the polymerizable region that includes dimethylmethacrylate and oligomethacrylate. According to the Examiner, the polymerizable macromer includes a core, an extension on each end, and an endcap wherein the core includes hydrophilic polyethylene glycol. The Examiner states:

Since all the elements recited in the claimed invention appear to be disclosed by Hubbell, *et al.* it is maintained that the features recited in the claimed invention, *i.e.* a stable interaction exists between the surface and the linker which comprises hydrogen bonds and which cannot be reversed by pH in the range of from 2-13 or temperatures up to 60C, are inherently taught by Hubbell, *et al.*

OA at 6-7.

The applicants respectfully traverse each of these rejections, and request that they not be applied to the new claims.

### Daniel

Daniel discloses lattices of polymers that are aqueous dispersions of polymers in particle form. The particle is made up of a "core" which represents 50% to 90% by weight of the particle. The core comprises cross-linked homo- or copolymers of vinyl monomers, including styrene, methylstyrene, vinyltoluene, ethylvinylbenzene or alkyl acrylates. The particles of Daniel also include a "periphery" which is 10% to 50% of the particle, and is formed by a vinyl or diene monomer and a monomer containing –CN groups which are copolymerized with the vinyl or diene monomer. The monomer containing the –CN group at the periphery is capable of covalently bonding to proteins such that the proteins are fixed and the lattice particle acts as a carrier. Thus, the Daniel device is (1) a vinyl polymer/copolymer ("core") polymerized to a (2) monomer containing a –CN group ("periphery"), which is itself linked to a protein.

### DeCrosta

DeCrosta teaches a drug delivery system that includes interpenetrating polymer networks. The interpenetrating polymer network is made up of a water swellable first polymer substrate in the form of hydrogel beads that are interpenetrated by a diffusion rate controlling membrane comprised of a second cross-linked polymer formed of the reaction product of an acrylic swelling agent and a cross-linking agent. The interpenetrating polymer network of the invention of DeCrosta is a combination of two polymers in network form, at least one of which (the second polymer) is synthesized and/or cross-linked in the immediate presence of the other (the first polymer, in the form of hydrogel beads).

The hydrogel beads disclosed as suitable for the first polymer are taught as being the hydrogels of U. S. Patent Nos. 4,423,099; 4,224,427; 4,056,496; 4,136,250; 4,379,864.

The second interpenetrating polymer is formed from the reaction product of (i) an acrylic swelling agent (which may be acrylic acid, methyl methacrylate, acrylic anhydride, ethylene, vinyl acetate, hydroxy ethylacrylate, methacrylate, vinyl pyrrolidone, vinyl chloride, methacrylate acid, acrylamide, hydroxyl propylmethacrylate, hydroxyethylmethacrylate, and butyl acrylate and (ii) a cross linking agent that is a monomer containing at least two vinyl groups.

### Hubbell

Hubbell teaches hydrogels of polymerized and cross-linked macromers. The hydrogels of Hubbell comprise hydrophilic oligomers having biodegradable monomeric or oligomeric extensions. The biodegradable extensions are terminated on free ends with endcap monomers or oligomers capable of polymerizing and cross-linking. The configuration of the hydrogel tissue contacting material of Hubbell is shown in Figure 1. The water soluble core shown by an unbroken line may be polyethylene glycol. From this water soluble core extend hydrolysable degradable extensions such as polyglycolides. On these extensions is located an endcap which may be an acrylate, and the broken lines show a water soluble hydrolysable portion which may be hyaluronate.

### None of the Cited References Anticipates the Claims

To anticipate an claimed invention, the reference cited by the Examiner must teach each element as recited in the claim either expressly or inherently. If the Examiner is asserting that an element is presently inherently, she has the burden of providing a reasonable technical basis that would have caused a person of skill to understand that the allegedly inherent element was present. None of Daniel, DeCrosta or Hubbell satisfies the “all elements” requirement, as each does not teach all elements of the invention.

The invention is an interactive system that includes at least three component (parts a (plastic material), b (linker), and c (substance) of, *e.g.*, claim 35). The claim recites that the component that are parts a and b are related to one another in a specific manner. Namely, a specific structural element (A) of the monomer of the plastic material interacts with a specific structural element (B) of the linker. The “interaction” comprises hydrogen bonds of a very specific nature -- they cannot be reversed by pH values in the range of from 2 to 13 or temperatures up to 60°C.

While the references cited by the Examiner contain many of the same component parts that could be used in the interactive system of the invention, none of the references teach that the component parts are associated with one another (i) at structural elements (A) and (B), and (ii) by an interaction that includes hydrogen bonds that cannot be reversed by pH values in the range of from 2 to 13 or temperatures up to 60°C. In Daniel, the lattice particle that is capable of

carrying proteins is made of a core and a periphery. The core component is associated with the periphery component by polymerization.

Similarly, the component parts of the Hubbell hydrogels are associated with one another by polymerization. As is known to a person of skill, polymerization requires the formation of covalent bonds. Hydrogen bonds and covalent bonds are not the same, and the specific hydrogen bonds that comprise the interaction between elements (A) and (B) of the invention are not disclosed either expressly or inherently in any of the cited references.

The drug delivery system of DeCrosta is an interpenetrating polymer network. The network results when the second polymer is polymerized in the presence of the first polymer, which is in the form of a hydrogel. Thus, the DeCrosta drug delivery system is a network of two interpenetrated polymers, woven or 'networked' together by the polymerization of the second polymer in the presence of the first. Thus, the association of the component parts of the DeCrosta drug delivery system is mechanical in nature, a result of the interpenetration occurring upon polymerization. It is not the specific interaction between elements (A) and (B) of the invention including the specifically recited hydrogen bonds.

In asserting the any of Daniel, DeCrosta, or Hubbell teaches each element of the invention, the Examiner has failed to consider the invention as a whole, and has merely sought out various prior art references which "anticipate" each of the component parts of the invention individually. The Examiner's argument that since each of the component part may be present in the prior art and the prior art has a similar purpose, all elements are "inherently" present is equally flawed. In the present case, the specific components taught in the art do not dictate or require the "interaction" of the invention, to the contrary, each specifically teaches that the recited interaction is not present, but rather that the association between the components is mechanical or covalent in nature.

Accordingly, for at least the reasons given above, none of Daniel, DeCrosta, or Hubbell teach anticipates the invention under § 102. It is requested that the Examiner reconsider and withdraw the rejections.

## CONCLUSION

In view of the foregoing, it is respectfully submitted that the applicants have distinguished the invention over the cited prior art. Reconsideration and allowance of pending claims 35-38, 42-47, and 50-55 at the earliest opportunity is earnestly solicited.

Respectfully submitted,

**ELKE BUCHA, et al.**

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